



JUL 23 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Geoffrey Sleeper  
Tiara Medical System, Inc.  
14414 Detroit Avenue, Suite 205  
Lakewood, OH 44107

Re: K012207  
Advantage™ Nasal Mask  
Regulation Number: 868.5905  
Regulatory Class: II (two)  
Product Code: 73 BZD  
Dated: July 12, 2001  
Received: July 16, 2001

Dear Mr. Sleeper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

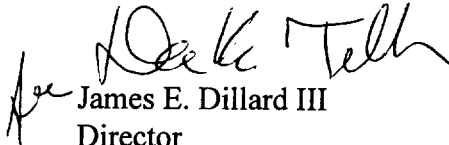
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have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
James E. Dillard III  
Director

Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Attachment 3 – Indications for Use Enclosure**

510(k) Number: K012207

Device Name: Tiara Medical Systems Advantage™ Nasal Mask

**Intended Use / Indications for Use:**

The Tiara Medical Systems Advantage™ Nasal Mask is intended to be used with positive airway pressure devices such as CPAP (Continuous Positive Airway Pressure), operating at or above 3 cmH<sub>2</sub>O for the treatment of adult obstructive sleep apnea.

**Environment of Use / Patient Population:**

The mask is intended for single patient use and re-use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.

(PLEASE DO NOT WRITE BELOW THIS LINE/CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K012207

Prescription Use ☒  
(per 21 CFR 801.109)

OR

Over the Counter Use ☐  
Optional Format 1-2-96